UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ALLISON OTTESEN, et al.,

Plaintiffs,

v.

HI-TECH PHARMACEUTICALS, INC.,

Defendant.

Case No. 19-cv-07271-JST

ORDER GRANTING MOTION TO CERTIFY ORDER FOR INTERLOCUTORY APPEAL AND MOTION TO STAY PENDING APPEAL

Re: ECF No. 75

Before the Court is Defendant Hi-Tech's motion to certify the Court's October 17, 2023 order lifting the stay of the case for interlocutory appeal and motion to stay pending appeal. ECF No. 75. The Court will grant the motions.

I. BACKGROUND

Because the facts are well-known to the parties and the Court has summarized Plaintiffs' allegations in detail in its prior orders, ECF Nos. 41, 70, the Court will not elaborate them here.

In sum, this case concerns the alleged use of DMHA[1] in supplements manufactured, distributed, and sold by Defendant Hi-Tech Pharmaceuticals, Inc. On November 20, 2020, the Court stayed the case on primary jurisdiction grounds, "pending a determination by the FDA regarding the classification of DMHA." ECF No. 56 at 6. Nearly three years later, Plaintiffs moved to lift the stay following an FDA website update that stated, in part, that "[a]fter further research and consideration, [the] FDA concluded that DMHA is an unsafe food additive" and "adulterated under the FD&C Act."[2] ECF No. 66 (quoting FDA, DMHA in Dietary Supplements

[1] The complaint uses "DMHA" as shorthand for the substance also called, variously, 2-Aminoisehptane HCI, 1,5-DMHA, 2-amino-6-methylheptane, 2-amino-5methylheptane, 1,5-Dimethylhexylamine, 2-Isooctyl amine, and Octodrine. ECF No. 1 at 8–9.

[2] The FD&C Act refers to the Federal Food, Drug, and Cosmetic Act.

(Mar. 6, 2023), https://www.fda.gov/food/dietary-supplement-ingredient-directory/dmha-dietary-supplements [https://perma.cc/BN87-K7JX]). On October 17, 2023, the Court lifted the stay. ECF No. 70. For ease of reference, the relevant excerpts of the order are the following:

> Hi-Tech correctly observes that Plaintiffs failed to notify the Court with seven days of the FDA's March 6, 2023 website update, which indicates either that Plaintiffs did not view the update as a final determination by the FDA or that they violated the Court's order to "notify the Court within seven days of a final determination by the FDA." ECF No. 56 at 6. In addition, the legislative history of the Dietary Supplement Health and Education Act, which is one of the bases of Plaintiffs' claims, indicates that if the FDA seeks "to declare a dietary supplement adulterated," it "would publish a notice in the Federal Register proposing to [do so] and setting forth the basis for their position that a substantial and unreasonable risk of illness or injury is presented." S. Rep. No. 103-410, at 35 (1994) (quoted with approval in *Rosas v. Hi-Tech Pharms*., No. CV 20-00433- DOC-DFM, 2020 WL 5361878, at *4 (C.D. Cal. July 29, 2020)). That process has not occurred in this case.
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> Nonetheless, the FDA website states that the agency has "concluded that DMHA is an unsafe food additive," and that it "considers dietary supplements containing DMHA to be adulterated." DMHA in Dietary Supplements. Nothing about this language appears tentative, nor—unlike the last time this question came before the Court—is there any indication in the record that the FDA's "decision-making is still ongoing." ECF No. 56 at 5. In the absence of any such evidence, the Court concludes that there no longer is a basis for a stay.

ECF No. 70 at 2–3. Following this Court's order lifting the stay, Hi-Tech filed the present motion requesting that the Court certify its October 17, 2023 order for interlocutory appeal pursuant to 28 U.S.C. § 1292(b) and enter a stay of all proceedings pending that appeal.

II. LEGAL STANDARD

The final judgment rule ordinarily provides that courts of appeal shall have jurisdiction only over "final decisions of the district courts of the United States." 28 U.S.C. § 1291. However, "[w]hen a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order." 28 U.S.C. § 1292(b). "The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such

order." *Id*.

"Certification under § 1292(b) requires the district court to expressly find in writing that all three § 1292(b) requirements are met." *Couch v. Telescope Inc.*, 611 F.3d 629, 633 (9th Cir. 2010). "Section 1292(b) is a departure from the normal rule that only final judgments are appealable, and therefore must be construed narrowly." *James v. Price Stern Sloan, Inc.*, 283 F.3d 1064, 1067 n.6 (9th Cir. 2002). To that end, "section 1292(b) is to be applied sparingly and only in exceptional cases." *In re Cement Antitrust Litig. (MDL No. 296)*, 673 F.2d 1020, 1027 (9th Cir. 1981), *aff'd sub nom. Arizona v. Ash Grove Cement Co.*, 459 U.S. 1190 (1983).

III. DISCUSSION

A. Motion to Certify Order For Interlocutory Appeal

The Court concludes that Hi-Tech has satisfied the requirements of 28 U.S.C. § 1292(b). Accordingly, Hi-Tech's motion will be granted.

1. Controlling Law

The first prong regarding the availability of interlocutory appeal requires that a "controlling question of law" be present. 28 U.S.C. § 1292(b). A "controlling" question of law may only be found in "exceptional situations in which allowing an interlocutory appeal would avoid protracted and expensive litigation." *In re Cement Antitrust Litig.*, 673 F.2d at 1026. A question of law is controlling if "the resolution of the issue on appeal could materially affect the outcome of litigation in the district court." *Id*. at 1027. "[A] mixed question of law and fact," by itself, is not appropriate for permissive interlocutory review. *Steering Comm. v. United States*, 6 F.3d 572, 575 (9th Cir. 1993).

Hi-Tech has asked for appellate review of the question "whether statements posted to an agency's website constitute 'final agency action' sufficient to justify lifting a stay previously entered based on the primary jurisdiction doctrine." ECF No. 75 at 12. Hi-Tech contends that this is a "question of law" that "should be answered by the Ninth Circuit." *Id.* at 12–13.

Plaintiffs focus much of their opposition arguing that "final agency action is not the appropriate standard under the primary jurisdiction doctrine." ECF No. 86 at 9. They assert that "the controlling factors under the primary jurisdiction doctrine are efficiency and whether there is

a need for agency expertise." *Id.* True, courts consider these factors in deciding whether the doctrine *applies* in the first instance. But the question before the Court when it lifted the stay was whether the FDA had made "a final determination" regarding the classification of DMHA. ECF No. 70 at 1. "[T]he finality requirement is concerned with whether the initial decisionmaker has arrived at a definitive position on the issue . . . . " *Darby v. Cisneros*, 509 U.S. 137, 144 (1993) (first alteration in original). For an agency action to be final, (1) there must be a "consummation of the agency's decision-making process" that is "not tentative or interlocutory in nature" and (2) "the action must be one by which 'rights or obligations have been determined,' or from which 'legal consequences will flow.'" *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997) (citations omitted). In its prior order lifting the stay, the Court reasoned that "nothing about [the website's] language appear[ed] tentative, nor—unlike the last time this question came before the Court—[was] there any indication in the record that the FDA's "decision-making [was] still ongoing." ECF No. 70 at 3.

The Court agrees with Defendant that the answer to "whether statements posted to an agency's website constitute 'final agency action'" is controlling to this litigation. ECF No. 75 at 12. If the stay remains lifted, litigation may proceed. Should the Ninth Circuit disagree, however, the case would likely remain stayed, possibly avoiding "protracted and expensive litigation" in the interim. *Id*. at 14 (quoting *In re Cement Antitrust Litig*., 673 F.2d at 1026). Therefore, this prong is satisfied.

2. Substantial Ground for Difference of Opinion

The second prong regarding the availability of interlocutory appeal requires that there be "substantial ground for difference of opinion." 28 U.S.C. § 1292(b). To determine whether there is a "substantial ground for difference of opinion," courts examine "to what extent the controlling law is unclear." *Couch*, 611 F.3d at 633. "[A] party's strong disagreement with the Court's ruling is not sufficient for there to be a 'substantial ground for difference.'" *Id*. (quotations omitted). A substantial ground for difference of opinion may exist where "the circuits are in dispute on the question and the court of appeals of the circuit has not spoken on the point, if complicated questions arise under foreign law, or if novel and difficult questions of first impression are

presented." *Id*. (quoting 3 Federal Procedure, Lawyers Edition § 3:212 (2010) (footnotes omitted)). That being said, "just because a court is the first to rule on a particular question or just because counsel contends that one precedent rather than another is controlling does not mean there is such a substantial difference of opinion as will support an interlocutory appeal." *Id*.

The Court acknowledges that the Ninth Circuit has not spoken directly on the issue of whether statements posted to the FDA's website constitute final agency action sufficient to justify lifting a stay previously entered based on the primary jurisdiction doctrine. Further, to the best of this Court's knowledge, no federal court has directly confronted this issue with regard to the FDA.

Plaintiffs argue that there is not a substantial ground for difference of opinion because "definitive, conclusive statements concerning the FDA's position with respect to certain products and/or claims is in line with Ninth Circuit precedent [sic]." ECF No. 86 at 13 (citing *Reid v. Johnson & Johnson*, 780 F.3d 952, 966–67 (9th Cir. 2015)). But the question before the Court now is not whether the FDA's statements were conclusive on the question of DMHA—the Court previously answered that question in the affirmative. Before the Court now is a separate inquiry: whether statements posted to the FDA's website may constitute "final agency action" sufficient to justify lifting a stay. *Bennett*, 520 U.S. at 178. There is substantial ground for difference of opinion as to that question.

The Court noted in its prior order that the legislative history of the Dietary Supplement Health and Education Act indicates that if the FDA seeks "to declare a dietary supplement adulterated," it "would publish a notice in the Federal Register proposing to [do so] and setting forth the basis for their position that a substantial and unreasonable risk of illness or injury is presented." S. Rep. No. 103-410, at 35 (1994) (quoted with approval in *Rosas v. Hi-Tech Pharms*., No. CV 20-00433- DOC-DFM, 2020 WL 5361878, at *4 (C.D. Cal. July 29, 2020)). The FDA did not provide such notice in this case. Based on this language, however, reasonable minds could differ on whether notice in the Federal Register is required to declare a substance adulterated, or if it is only one possible avenue the FDA may pursue to declare a substance adulterated. This provides an additional basis for finding the second prong satisfied.

3. Materially Advance Litigation

The third and final prong in the interlocutory appeal standard requires a showing that the grant of immediate appeal "may materially advance the ultimate termination of the litigation." 28 U.S.C. § 1292(b). "[N]either § 1292(b)'s literal text nor controlling precedent requires that the interlocutory appeal have final, dispositive effect on the litigation, only that it 'may materially advance' the litigation." *Reese v. BP Exploration (Alaska) Inc.*, 643 F.3d 681, 688 (9th Cir. 2011).

Of the three factors, this one is the easiest to resolve. This is primarily because "the considerations of this factor overlap significantly with the first one," whether the issue presents a controlling question of law. *Rollins v. Dignity Health*, No. 13–CV–01450–TEH, 2014 WL 6693891, at *4 (N.D. Cal. Nov. 26, 2014). As discussed above, if the stay remains lifted, litigation may proceed. But if the Ninth Circuit disagrees, it may reinstate the stay for an indeterminate amount of time. Interlocutory appeal would provide the Court with necessary clarity that would materially advance this litigation. Thus, the third prong, too, is satisfied.

B. Motion to Stay Pending Interlocutory Appeal

Having concluded that it is appropriate to certify the order for interlocutory appeal, the Court now addresses Hi-Tech's request for a stay pending appeal. When determining if a stay is appropriate, courts consider (1) "the possible damage which may result from the granting of a stay"; (2) "the hardship or inequity which a party may suffer [if the case is allowed] to go forward"; and (3) "the orderly course of justice measured in terms of the simplifying or complicating of issues, proof, and questions of law which could be expected to result from a stay." *Kuang v. United States Dep't of Def.*, No. 18-CV-03698-JST, 2019 WL 1597495, at *2 (N.D. Cal. Apr. 15, 2019) (citing *Landis v. North American Co.*, 299 U.S. 248 (1936)).

Although the Court recognizes that this case has already been stayed for three years, the Court finds that an additional stay is warranted. If the case were to proceed pending Ninth Circuit review, "significant and potentially unnecessary" resources may be invested by both parties. *Gustavson v. Mars, Inc.*, No. 13-CV-04537-LHK, 2014 WL 6986421, at *3 (N.D. Cal. Dec. 10, 2014). Finally, the Court believes that "judicial economy will best be served" by staying this case,

as "the Ninth Circuit's decision is likely to provide substantial guidance" that may "materially alter the Court's decisions in the instant case." *Id.*

CONCLUSION

In sum, the Court finds it appropriate to stay the proceedings while the order certifying interlocutory appeal is reviewed by the Ninth Circuit. The parties are ordered to notify the Court within 10 days of receipt of a decision from the Ninth Circuit Court of Appeals.

IT IS SO ORDERED.

Dated: February 13, 2024

JON S. TIGAR
United States District Judge